DOUBLE PATENTING REJECTION

The instant Application (Serial No. 10/525,255) is owed by the University of Texas System and licensed exclusively by Endothelix. Provisional application No. 60/405,352 is also owned by the University of Texas System. Application Serial No. 11/871,901 referenced by the Examiner is commonly owned by the University of Texas System and Endothelix. The 11/871,901 application is a continuation in part of 10/525,255.

The invention of the instant application precedes the invention of co-pending application. At issue are the claims of the instant application claiming priority to August 23, 2002. The later filed disclosure of S/N 11/871,901 is not a reference against the instant application.

As the examiner acknowledges, the claims of the cited co-pending application differ from the instant application in that the claims of the co-pending application "are specifically for assessing vascular function." The claims of the instant application are not so limited.

SECTION 112 FIRST PARAGRAPH REJECTIONS

The Examiner has rejected claim 1 through 22 under 35 U.S.C. 112, first paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention. The Applicant respectfully traverses the Examiner's objection. It is the Applicant's position that the new claims clearly describe the invention to a person skilled in the technology or profession as it relates to vasodilating stimulants.

New claim 23 teaches (i) recording a patient's temperature distal to a selected site for creating an arterial occlusion, (ii) creating the occlusion for a pre-determined period of time and thereby creating a vasodilating stimulant, (iii) removing the occlusion (iv) continuing to record the temperature and (iv) assessing the patient's endothelial function based upon the recorded changes in temperature. Claim 24 states the vasodilating stimulant to be the occluded blood flow.

The Examiner has asserted a description of the components necessary for the functioning of the invention are lacking. The Applicant disagrees. One example of the component for creating the occlusion is described in the specification as a cuff placed on an arm, wrist, finger or leg. In one embodiment, temperature is measured by sensors placed on the tip of a finger.

Further, mechanisms for measuring body temperature and creating vascular occlusions are well known to persons skilled in the technology or profession.

DRAWINGS

The Examiner has rejected Applicant's Figure 4 as new matter based upon the assertion that the figure was improperly incorporated by reference. The Applicant traverses the Examiner's rejection.

The Application contains a claim for priority of a prior-filed provisional application, i.e., "Provisional application No. 60/405,352, filed on Aug. 23, 2002."

Figure 4 was included in provisional application 60/405,352 as filed.

The clear text of 37 CFR 1.57 states:

> "(a) Subject to the conditions and requirements of this paragraph, if all or a portion of the specification or drawing(s) in inadvertently omitted from an application, but the application contains a claim under ... §1.78 for the benefit of a prior-filed provisional, nonprovisional, or international application, that was present on the filing date of the application, and the inadvertently omitted portion of the specification or drawing(s) is completely contained in the prior-filed application, the claim under §1.55 or §1.78 shall also be considered an incorporation by reference of the prior-filed application as to the inadvertently omitted portion of the specification or drawing(s)." (Emphasis added.)

Therefore Figure 4 must be deemed incorporated by reference based upon the prosecution file history.

Further, the device subject of Figure 4 is described within the specification. The specification states the monitored hemodynamic parameter may be a parameter such as blood temperature. See para. [0020] of the substitute specification. A vasodilating stimulant may comprise compressing the brachial artery. The vasodilating stimulant can also comprise occluding blood flow in the arm. See para. [0021]. Temperature sensors can be placed on the patient's fingertips or arm to monitor the resulting change in temperature. See para. [0022]. The specification further states the occlusion may be created by inducing cuff pressure on an arm, etc. See para. [0030].

As illustrated in the above paragraph, no new matter is added by Figure 4.

112 SECOND PARAGRAPH REJECTIONS

The Examiner asserts that the now cancelled claims are ambiguous because one cannot ascertain what particular vasodilator stimulants Applicant is claiming that are compatible with the instant invention. In response to the Examiner's restriction requirement, the Applicant elected the specie of the vasodilator as occlusion of blood flow. The Applicant further elected the hemodynamic parameter to be temperature. New claim 23 includes "compressing the patient's artery to impede distal blood flow and thereby create a vasodilating stimulant".

The vasodilating stimulant is clearly and unambiguously stated in the claims.

103 REJECTION

The Examiner has rejected the now cancelled claims as being unpatentable over Drzewiecki et al in view of Goor. The Applicant respectfully asserts that Drzewiecki and Goor are not applicable to the Applicant's elected invention.

Drzewiecki utilizes a combination of (i) an inflatable blood pressure cuff with a hand pump and blood pressure gauge and (ii) a plurality of equations for computing arterial volume compliance, arterial area compliance and arterial lumen area. The apparatus is a plethysmograph, i.e., an instrument for determining and registering variation in the size of an organ, limb, or part resulting from changes in the amount of blood present or passing through it. See Merriam-Webster OnLine.

Drzewiecki contains no component for measuring temperature.

Goor discloses a method and apparatus for providing an indication of myocardial ischemia or sleep apnea. The apparatus includes a finger probe which is designed to apply pressure. The pressure on the finger is raised to a pressure which is "sufficient to unload the arterial walls and to prevent venous pooling". In the stated preferred embodiment, the pressure is automatically raised to 70 mm Hg. Col 18, line 62 -67. It should be noted that in this pressure environment, the finger inserted into the pressurized finger probe and drained of blood is unsuitable for measurement of temperature.

As stated above, neither Drzewiecki nor Goor disclose critical elements of the Applicant's invention, i.e., monitoring temperature. With due respect to the Examiner, a passing reference to an optional addition of heat to a glove is not equivalent to the critical element of the Applicant's invention to monitor temperature. The addition of heat would be inconsistent with the Applicant's invention.

Further the Applicant does not employ a plethysmograph. Although the full definition of the word is stated above, it is sufficient that a plethysmograph is a device for measuring volume. The Applicant is not measuring volume. The Applicant is monitoring changes in temperature in response to vasodilating events.

Neither Drzewiecki nor Goor provide any teaching or suggestion of the Applicant's method. There must be some apparent reason to combine the known elements in the fashioned claimed and that reason must be explicit. See Ex parte Whalen II, No. 2007-4423 (Bd. Pat. App. & Int. July 23, 2008)

SUMMARY

The Applicant has amended paragraphs of the specification to clearly identify where in the incorporated provisional application text has been incorporated by reference. Claims have been cancelled and new claims incorporated. The new claims clearly delineate the subject matter of the elected invention. The Applicant has further analyzed the prior art patents cited by the Examiner. The Applicant has shown that the cited patents do not contain the elements of the Applicant's invention.

Submitted this 16th day of April, 2010

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CERTIFICATE OF TRANSMISSION

The undersigned attests based upon personal knowledge that the above document was transmitted through the EFS-Web system on April 16, 2010.

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